REMARKS

A. Preliminary Remarks

Following entry of the present amendment, claims 1-3, 5, 7-16, 25, 27-28, 36, 38, and 40-48 will be pending in the application. Claims 1, 2, 5, 12, 13, 16, 25, 27-28, 36, 38, 40, and 43-44 have been amended herein. Support for the amendments are found throughout the application-as-filed and, thus, do not introduce new matter. Claims 1-12, 28-39, and 42 are under examination, with claims 13-27, 40-41, and 43-48 withdrawn as being directed to non-elected inventions.

B. The rejection of claims 1-12, 28-39 and 42 under 35 U.S.C. § 112, first paragraph, for lack of written descriptive support should be withdrawn

The Examiner supported the rejection by asserting that adequate written description requires disclosure of sufficient distinguishing identifying characteristics of the invention. As noted by the Examiner, the standard articulated in Vas-Cath Inc. v. Mahurkur, 935 F.2d 1555, ___, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991) is whether one of ordinary skill in the art can recognize that the inventor(s) invented what is now claimed. The remainder of the support for the rejection provided by the Examiner focuses on case law addressing specific nucleic acid product claims or addressing a disclosure outlining goals achievable if the invention were made. In response, Applicants traverse.

The claims under examination are not drawn to particular nucleic acids. As amended, claims 1-12 and 42 are drawn to a compound that is (1) anti-inflammatory, (2) heat-stable, (3) cytoprotective, (4) an inhibitor of NF-κB, and (5) is derived from a Lactobacillus bacterium. These properties characterize the compound recited in each of claims 1-12 and 42. Claims 28-39 are drawn to cognate pharmaceutical compositions, as is apparent from the ultimate dependency of each of these claims on claim 1. The supporting disclosure clarifies that the inventors had not purified a nucleic acid that was then claimed without providing its primary structure. Rather, the inventors identified a compound produced by Lactobacilli and characterized that compound to the extent of determining a number of identifying characteristics, as recited in the pending claims. Even if this compound is found to be a nucleic acid, moreover, the Examiner has correctly acknowledged that written description can be satisfied by the provision of sufficient identifying characteristics, and not just by providing a complete primary structure of a nucleic acid compound. The law does not require that

inventors retain keep their product-based inventions to themselves until a primary structure is known; rather, the written description requirement demands that one demonstrate to those of skill that the inventor invented, and is thereby in possession of, that which is claimed. The instant specification discloses the identification of a compound that is (1) anti-inflammatory, (2) heat-stable, (3) cytoprotective, (4) an inhibitor of NF-κB, and (5) is derived from a Lactobacillus bacterium, and that is precisely what is claimed. Applicants submit that one of skill would recognize that the inventors invented what is now claimed and further submit that the claims as amended distinguish what is now claimed from what is not claimed. Accordingly, Applicants submit that the Examiner has not met the burden of establishing a *prima facie* basis for rejecting the claims as lacking adequate written descriptive support based on reliance placed on the cited case law relating to nucleic acid claims, i.e., Fiers v. Ravel, 984 F.2d 1164, ___, 25 U.S.P.Q.2d 1601, 1606 (Fed. Cir. 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991).

The reliance placed on case law asserting that disclosures merely outlining goals to be achieved by the claimed subject matter is also misplaced. The issue in In re Wilder, 736 F.2d 1516, 1`521, 222 U.S.P.Q. 369, 372-373 (Fed. Cir. 1984) was whether the original specification provided written descriptive support for a reissue claim broadened by dropping a requirement for scanning and indexing means to exhibit "synchronism." In the present matter, the Examiner is rejecting original claims that could not have been broadened. Additionally, the instant specification provides support for each of the identifying characteristics recited in the claims and noted above.

For the foregoing reasons, Applicants submit that the Examiner has not satisfied the burden of establishing a *prima facie* basis for rejecting claims 1-12, 28-39 and 42 under 35 U.S.C. § 112, first paragraph, for lack of written description and the rejection should be withdrawn.

C. The rejection of claims 1-12, 28-39 and 42 under 35 U.S.C. § 112, first paragraph, for lack of enablement should be withdrawn

The Examiner acknowledged that the rejected claims were enabled for an extract from a medium, but because enabling support for an isolated compound was assertedly lacking, the scope of enablement was not commensurate in scope to the claims. In response, Applicants traverse.

The Examiner asserted in support of the rejection that the application only describes an extract and does not disclose an isolation procedure. The Examiner further states that "in light of the grave unpredictability in the art with regard to isolate each single compound from an extract of a living microorganism, elucidate each structure of the compound, and co-relate each compound with claimed functional activity, the Applicant is not enabled for an isolated compound as instantly claimed. Even the most skilled of artisans would need to quantify each product for constituents as well as medicinal efficacy."

Applicants initially note that "isolated" does not mean purified to homogeneity, as the Examiner has assumed. An "isolated" compound can be a compound separated from a single composition with which it is normally found. Thus, a medium extract containing a compound from a Lactobacillus bacterium satisfies the ordinary meaning of an isolated compound. For this reason alone, the rejection should be withdrawn.

Beyond the preceding dispositive point, Applicants submit that the support provided by the Examiner is misplaced in that it fails to address whether the claimed subject matter is enabled. The Examiner addresses the grave unpredictability of isolating each single compound from an organism, which is irrelevant to whether the subject matter of the pending claims is enabled. The claims do not recite an isolated form of each compound of an organism. The claims are drawn to a compound (or cognate pharmaceutical composition) exhibiting at least five identifying characteristics, i.e., (1) is anti-inflammatory, (2) is heat-stable, (3) is cytoprotective, (4) is an inhibitor of NF-κB, and (5) is derived from a Lactobacillus bacterium. The vast majority of compounds isolable from any organism would not exhibit this set of identifying characteristics, and the Examiner has not contended otherwise. If, on the other hand, the Examiner was referring to a single compound in the statement addressing the grave unpredictability of isolating each single compound, then Applicants request clarification of the references in that sentence to correlating "each compound with claimed functional activity" and "elucidat[ing] each structure of the compound." The Examiner also asserted that even skilled artisans "would need to quantify each product for constituents as well as medicinal efficacy." If the Examiner is arguing the need to provide activity determinations and dosages, Applicants submit that these determinations are made as a matter of routine in the art and will vary depending upon the circumstances, as would be known in the art. Those of skill in the art know that activity and dosage determinations need to be made (using routine procedures) for each application and

will vary depending upon the particular preparation of isolated compound/pharmaceutical composition as well as upon the subject to receive the material.

For all of the foregoing reasons, Applicants submit that the Examiner has not established a *prima facie* basis for rejecting claims 1-12, 28-39 and 42 under 35 U.S.C. § 112, first paragraph, for lack of enablement, and the rejection should be withdrawn.

D. The rejection of claims 2, 12, and -39 under 35 U.S.C. § 112, second paragraph, for indefiniteness should be withdrawn

The Examiner asserted that claim 2 is indefinite in reciting "the" probiotic-conditioned medium without sufficient antecedent basis. Applicants submit that this basis for rejecting claim 2 has been rendered moot by the amendment to claim 2. The Examiner also asserted that claim 2 requires a compound present in an ether-extracted fraction of the probiotic-conditioned medium and, therefore, could not satisfy the claim 1 limitation to an isolated compound, as it must in view of the dependency of claim 2 on claim 1. Applicants submit that "isolated" does not have the narrow meaning ascribed to it by the Examiner. A compound is "isolated" if it is separated from one or more materials, such as compounds, with which it is normally associated. Thus, an "isolated" compound can be a compound found in a conditioned medium, including an ether extract of such conditioned medium. Accordingly, the rejection of claim 2 as indefinite may properly be withdrawn.

The Examiner also rejected claims 12 and 39 for reciting a trademark. In response, Applicants have amended claim 12 and canceled claim 39. The amendment to claim 12 substitutes the identities of the bacteria for the trademarked term VSL#3®, and is supported at page 5, lines 27-31 of the specification. Accordingly, the rejection of claims 12 and 39 as indefinite may properly be withdrawn.

E. The rejection of claims 1-3, 12, 28-30 and 39 as anticipated under 35 U.S.C. § 102(e) over Versalovic (US2004/0208863) should be withdrawn

In rejecting claims 1-3, 12, 28-30 and 39 as anticipated by Versalovic, the Examiner asserted that the reference discloses the administration of probiotic bacteria to treat infection and inflammatory bowel disease. The Examiner further asserted that lactic acid bacteria inherently secrete lactic acid, and that acid can be used as an anti-inflammatory agent and lactic acid is extractable in ether. In response, Applicants traverse.

Claim 1, and all rejected claims dependent thereon (i.e., claims 2, 3, and 28), are limited to an "isolated" compound, i.e., a compound separated from at least one material (e.g., compound) with which it is normally associated. Use of a lactic acid bacterium to deliver lactic acid means that the lactic acid being delivered is not "isolated," as required by the pending claims. In addition, the Examiner has not shown that lactic acid is an inhibitor of NF-κB activation. Accordingly, the Examiner has failed to establish a *prima facie* basis for rejecting claims 1-3 and 28 as anticipated under 35 U.S.C. § 102(e) over Versalovic. The remaining claims subject to rejection on the instant grounds, claims 29, 30 and 39, have been canceled by amendment herein.

For the foregoing reasons, Applicants submit that the rejection of claims 1-3, 28-30 and 39 under 35 U.S.C. § 102(e) over Versalovic has been overcome-in-part and rendered moot-in-part and the rejection should be withdrawn.

F. The rejection of claims 1-3, 12, 28-30 and 39 as anticipated under 35 U.S.C. § 102(e) over Raz (US2005/0180962) should be withdrawn

The Examiner asserted that Raz disclosed the use of inactivated probiotic bacteria (VSL#3®) in the treatment of gastroinstestinal inflammation, and that the composition of inactivated bacteria must be compatible with maintaining the viability of lactic acid bacteria. The Examiner further asserts that lactic acid bacteria inherently secrete lactic acid, which is ether soluble. In response, Applicants traverse.

A universal limitation of the rejected claims is that the compound be "isolated," and Raz discloses the administration of probiotic bacteria themselves. Thus, Raz does not teach an "isolated" compound and, for this reason alone, the rejection should be withdrawn.

Raz also is silent with respect to whether a compound of a probiotic bacteria is an inhibitor of NF-κB activation, and the Examiner has not established that inhibition of NF-κB activation is an inherent property of a compound of probiotic bacteria.

For the foregoing reasons relating to the failure of Raz to teach an "isolated" compound and the failure to establish that any "isolated" compound of probiotic bacteria is an inhibitor of NF-κB activation, Applicants submit that the Examiner has not established a *prima facie* basis for rejecting any of claims 1-3, 12, 28-30 and 39 under 35 U.S.C. § 102(e) over Raz and the rejection should be withdrawn.

G. Conclusion

For all of the foregoing reasons, Applicant submits that all outstanding rejections have been overcome and claims 1-12, 28-39 and 42 are in condition for allowance. An early notice thereof is respectfully solicited.

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Respectfully submitted,

By _____

William K. Merkel, Ph.D.
Registration No.: 40,725
MARSHALL, GERSTEIN & BORUN LLP
233 S. Wacker Drive, Suite 6300
Sears Tower
Chicago, Illinois 60606-6357
(312) 474-6300
Attorney for Applicant